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# 31st Bethesda Conference

## Emergency Cardiac Care (1999)
## September 13–14, 1999

**EXHIBIT L**

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**BETHESDA CONFERENCE REPORT**

# 31st Bethesda Conference: Emergency Cardiac Care (1999)*

Gordon A. Ewy, MD, FACC, *Conference Co-Chair*
Joseph P. Ornato, MD, FACC, FACEP, *Conference Co-Chair*

This Conference, sponsored by the American College of Cardiology, was held at the Heart House, Bethesda, Maryland, September 13–14, 1999.

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**31ST BETHESDA CONFERENCE**

# Emergency Cardiac Care: Introduction

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There are more than five million visits to Emergency Departments in the U.S. each year for evaluation of chest discomfort or other symptoms suggesting acute cardiac ischemia. These evaluations generate over $10 billion in hospital costs alone. In addition, over one million Americans have an acute myocardial infarction each year, and >250,000 people die of sudden, unexpected cardiac arrest.

Treatment of these conditions can be broadly termed "Emergency Cardiac Care." The American College of Cardiology has recognized this specialized area for decades. In fact, the 13th Bethesda Conference in 1981 was devoted to this subject (1). At that time, the principal focus was on the identification and management of patients with an acute cardiac emergency. Consensus guidelines were developed for "optimal emergency cardiac care before hospital admission, in the Emergency Department, and in the 6 h after hospital admission."

Since then, there have been major advances in the prehospital and in-hospital treatment of patients who have an acute coronary syndrome or who experience sudden, unexpected cardiac arrest. Prehospital care has improved markedly with the development of effective Emergency Medical Services (EMS) systems. Out-of-hospital defibrillation capability, in its relative infancy in 1981, has become the standard of care of first-responding fire engine companies and ambulances in most urban and suburban locales. Now some cities, such as Rochester (Minnesota), Pittsburgh and Cincinnati, even equip law enforcement officers with automated external defibrillators. We now have security officers in most Las Vegas casinos and airline flight attendants aboard many U.S. commercial aircraft who are trained and equipped to defibrillate cardiac arrest victims.

The 31st Bethesda Conference represents consensus opinions and recommendations of experts from a variety of disciplines on 1) the initial management of patients with sudden, unexpected cardiac arrest; 2) the initial evaluation and treatment of patients who present with symptoms suggesting the presence of an acute coronary syndrome; and 3) the facilitation of emergency cardiac care research requiring a waiver of informed consent. The principal focus of the conference was not on the development of clinical practice guidelines, but rather on a modified Delphi approach used to develop consensus opinions and recommendations on critical questions for which absolute or hard data are incomplete. Conference deliberations occurred in each of the three areas just noted. Specific discussions on the initial evaluation and treatment of patients with symptoms suggesting the presence of an acute coronary syndrome were divided into prehospital and in-hospital components.

Since 1981, there have been significant advances in cardiopulmonary resuscitation (CPR) and defibrillation. Although there is now clear evidence showing that bystander CPR significantly increases neurologically intact survival from cardiac arrest, several studies have documented reluctance on the part of the general public to perform mouth-to-mouth resuscitation on a stranger (2–4). A major topic of discussion at the 31st Bethesda Conference was whether the current national CPR guidelines for lay persons should be simplified, by not including a recommendation for bystanders to perform mouth-to-mouth resuscitation. Surprisingly, there is an increasing body of scientific evidence suggesting that it may not be essential to provide such ventilation during the first few minutes of cardiac arrest due to ventricular fibrillation (VF) (5–7). The present state of knowledge supports consideration of an etiology-based approach for CPR: 1) ABC CPR for asphyxial cardiac arrests and 2) chest-compression-only CPR for initial treatment of VF by the lay public. Perhaps the advancement that will have the greatest impact has been the development of the automatic external defibrillator. Specific recommendations are made (see later outline).

There have also been major advances in the recognition and treatment of patients with an acute coronary syndrome. Several of these advances were discussed in detail at the 31st Bethesda Conference, and several new recommendations were made regarding application of these new therapies in the prehospital and Emergency Department setting. There are detailed discussions on the complex issue of how to evaluate patients with chest discomfort, as well as a review of the diagnostic technologies and approaches to the initial management of patients with a suspected acute coronary syndrome.

Despite these advances, further progress has been hindered by the difficulty of performing emergency care research on impaired human subjects who are not able to give informed consent. This is particularly problematic in the area of cardiac arrest research, where all of the patients are unconscious and where promising new drugs or devices must be used early if they are to have any hope of success. In most cases, there is insufficient time to contact the family member to get consent. In 1996, Congress issued "Final Rules" (21 CFR 50.24) allowing for a waiver of informed

consent under very limited circumstances. Unfortunately, these rules have also created a new set of obstacles for researchers. Specifically, they require a vaguely defined community consultation and a public disclosure program. At the 31st Bethesda Conference, there were extensive discussions on this topic, and substantive new recommendations have emerged.

Finally, perhaps the most significant element of this exciting conference was the multidisciplinary representation of its participants. In 1981, cardiologists dominated the conference. In 1999, cardiologists still accounted for the largest percentage of participants. However, for the first time at a Bethesda Conference, there were a large number of emergency physicians. In addition, the conference included internists, family practitioners, prehospital care and/or fire service personnel, representatives of government agencies (including the National Heart, Lung, and Blood Institute of the National Institutes of Health and the Food and Drug Administration [FDA]), pediatricians, specialists in nuclear cardiology and echocardiography, basic science researchers, nurses, epidemiologists and educators. The recommendations derived from this exciting conference truly represent a broad range of relevant perspectives.

The Steering Committee of the 31st Bethesda Conference recommends that the American College of Cardiology formally endorse the following:

1. An educational program for the public and Institutional Review Boards (IRBs) on the importance of and the means to obtain a waiver of informed consent for research on patients who have emergency cardiac conditions.
2. Physician education on how to cost-effectively risk stratify the heterogeneous groups of patients who present with signs and/or symptoms of an acute coronary syndrome.
3. Patients with myocardial infarction and hemodynamic compromise, cardiogenic shock or other high risk criteria should be triaged to medical facilities that have 24 h staffed cardiac care services including emergency revascularization (percutaneous coronary intervention and coronary artery bypass graft surgery) and hemodynamic support available, provided ambulance transport duration is not excessive (>30 min). Triage should be performed as soon as possible, preferably in the field or in the nearest Emergency Department, depending on the medical community.
4. There is now compelling evidence that automatic external defibrillators (AEDs) can be safe and effective when used by first responders, particularly if the time for traditional EMS response is too long.
5. Continued research is needed in all areas of emergency cardiac conditions, including each link in the chain of survival.

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## TASK FORCES

# Task Force 1: Cardiac Arrest

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Out-of-hospital or prehospital sudden cardiac arrest accounts for an estimated 250,000 events each year (8). The majority occur secondary to cardiac arrhythmias. A small number, however, are due to asphyxia. The importance of bystander CPR and early defibrillation in survival from out-of-hospital cardiac arrest has been well documented. Survival rates as high as 90% have been seen with early defibrillation within the first minutes of cardiac arrest (9). The likelihood of meaningful survival to hospital discharge decreases by ~10% per minute thereafter. This has led to the concept of the "chain of survival": early access, early CPR, early defibrillation and early advanced life support. Each link is needed to improve cardiac arrest survival rates. Geographic constraints, population density and EMS organizations are associated with meaningful survival rates from out-of-hospital cardiac arrest from as low as 0% to as high as 44% (10). Survival rates of ≤10% are the norm in many areas.

Recent studies have shown the changing demographics of out-of-hospital cardiac arrest (11–13). The incidence of primary VF is declining, whereas the initial cardiac arrest rhythm is increasingly bradyasystolic. This parallels an increase in both the age-related and concurrent comorbid heart diseases, especially congestive heart failure, in the population of cardiac arrest victims.

## BASIC LIFE SUPPORT CPR: IMPROVING BYSTANDER CPR BY LAY RESCUERS

Standard, basic CPR (ABC CPR) is a coordinated integration of Airway management, rescue Breathing and chest compression-induced Circulation. This technique has proven to be life saving. However, CPR is performed infrequently by bystanders, and when it is performed, the quality is often disappointing. Insufficient force, inadequate rate and interruption of chest compressions are particularly significant problems. It is increasing clear that ABC CPR is a complex psychomotor technique, and therefore it is difficult to teach, learn, remember and perform under the best set of circumstances. New educational approaches, including video-based and home-learning systems, with more opportunity for skill mastery, are under investigation to address this dilemma (14). A significant effort to educate family members of high risk individuals is also warranted. The need to simplify basic life support (BLS) CPR is now well recognized. It has been documented that lay persons can neither remember nor perform ABC CPR as presently taught (15–18). Accordingly, proving the efficacy of simplified techniques should be a high priority.

**Routes to CPR simplification.** Existing data support several simplifications in BLS. Instruction to place the rescuer's hands "in the middle of the victim's chest and push" have resulted in hand positioning comparable to that of the previous method of careful landmark identification and measurement from the xiphoid process (19). European studies have shown the futility of asking lay persons, paramedics and even some physicians to judge the presence or absence of a pulse in assessing for adequate circulation (19,20). Elimination of the pulse check seems reasonable.

Cardiopulmonary resuscitation with chest compressions only (i.e., no assisted ventilation) has been proposed as one simplified technique that may encourage increased bystander CPR. Such a modification makes CPR easier to learn and to master, and it alleviates the fears and concerns associated with mouth-to-mouth contact. Animal studies have established that prompt initiation of chest compressions without assisted ventilation for 8 to 12 min can be as effective as ABC CPR with respect to 24 h survival and neurologic outcome after VF (21–25). Immediately after an acute fibrillatory cardiac arrest, aortic oxygen and carbon dioxide concentrations do not vary from the prearrest state, because there is no blood flow and aortic oxygen consumption is minimal. When effective chest compressions are initiated, this oxygenated blood flows from the aorta to the coronary circulation. Moreover, chest compression–induced gas exchange and active gasping during CPR are well documented (22,23,25). Importantly, these studies have documented no outcome disadvantage with less than optimal gas exchange from chest compressions alone, particularly when associated with active gasping during CPR.

Two important clinical studies support the use of chest-compression-only CPR for VF cardiac arrest. The Belgian Cerebral Resuscitation Group (26) prospectively evaluated 3,053 prehospital cardiac arrest victims. Physicians on the ambulance evaluated the quality and efficiency of bystander CPR. Good-quality chest-compression-only CPR and good-quality chest compressions plus mouth-to-mouth rescue breathing were comparably efficacious, and both were more effective than no bystander CPR.

Hallstrom et al. compared chest compressions alone to chest compressions plus assisted ventilation in the setting of dispatcher-directed telephone-assisted bystander CPR when the dispatchers determined that the bystander or caller did not know CPR (A. Hallstrom, personal communica-

tion, September 9, 1999). They randomly instructed these nearly 500 bystanders to provide chest compressions alone or chest compressions plus assisted ventilation. Survival to hospital discharge was 10% after chest compressions plus assisted ventilation and 14.5% after chest compressions alone ($p = 0.09$). Chest compressions alone was certainly not worse than chest compressions plus assisted ventilation, and the trend suggests it might be better.

Optimal BLS for asphyxial arrests is quite different. Asphyxia results in progressive oxygen consumption and carbon dioxide and lactate production before cardiac arrest. Therefore, adequate myocardial oxygen delivery during CPR for an asphyxial cardiac arrest requires re-establishment of arterial oxygenation and improvement of pH through adequate gas exchange in the lungs, as well as myocardial perfusion. Chest compressions plus rescue breathing is the treatment of choice for asphyxial arrest. However, laboratory and clinical experience suggests that patients with asphyxial cardiac arrest can sometimes be resuscitated with ventilation alone or compressions alone, despite a history of pulselessness and unresponsiveness (i.e., it is better to do "something" than "nothing") (27).

The present state of knowledge supports consideration of an etiology-based approach for CPR: 1) ABC CPR for asphyxial cardiac arrests and 2) chest-compression-only CPR for the initial treatment of VF by the lay public. Patients with witnessed sudden collapse and adults with unwitnessed arrests could be assumed to have VF, whereas patients with a submersion event or a foreign body aspiration or children with an unwitnessed arrest should be assumed to have an asphyxial arrest.

**Defibrillation first versus CPR first by the lay health care provider.** Ventricular fibrillation is uniformly fatal without defibrillation. Immediate defibrillation is the treatment of choice for a short episode of VF; the success of defibrillation decreases dramatically with the passage of time, presumably because of continued ischemia and progressive imbalance of myocardial oxygen supply and demand. Conversion to a perfusing rhythm with the first series of countershocks is a major determinant of survival from VF (28), yet the rate of such conversion with the first shock diminishes over time. Should a brief period of CPR be provided before defibrillation attempts for prolonged VF? Experimental animal studies have suggested that precountershock CPR for prolonged cardiac arrest can improve the defibrillation rate and rate of initial successful resuscitation as compared with immediate defibrillation attempts (29).

A recent prospective, observational investigation suggests that precountershock CPR for 90 s improves survival (30). After routine availability of AEDs, the overall survival rate from prehospital VF did not improve in Seattle, despite a 3 to 4 min shortened time to defibrillatory shock in most cases. Accordingly, Cobb et al. (30) compared an EMS protocol to provide an initial period of ~90 s of CPR before automated analysis of cardiac rhythm with defibrillation first. Survival improved from 24% (155 of 639) to 30% (142 of 478) ($p = 0.04$). As predicted, the survival benefit was more impressive when the initial response interval was >4 min (17% [56 of 321] vs. 27% [60 of 220]) ($p = 0.01$).

## MANAGEMENT OF VF/VT

### *Before Hospital Admission*

**Need for prospective, randomized trials.** Prospective, randomized trials need to be designed and funded to assess the effectiveness of BLS/defibrillator capability in diverse settings. Studies should follow the Utstein style and must determine the effect of any changes on the eventual survival of an integrated functioning individual; for this, particular attention needs to be given to the reporting of neurologic outcomes. The characteristics of the population being served by the EMS system must be well defined. Intervals from collapse to bystander CPR and collapse to defibrillation must be carefully assessed. Finally, all aspects of the links in the "chain of survival" need to be carefully documented. All these data points, in the Utstein template, are required if we are to compare the results of one study with those of another. Armed with such data, the medical profession will be in a better position to advise government and private industry as to the most efficacious and cost-effective manner of addressing the challenge of out-of-hospital cardiac arrest.

**Early defibrillation.** USE OF AEDS BY FIREFIGHTERS AND EMERGENCY MEDICAL TECHNICIANS. The development of AEDs has been a major medical advance. Their development not only holds the promise of early defibrillation, but also decreases the level of training necessary for personnel to defibrillate the out-of-hospital cardiac arrest victim. Since 1979, emergency medical technicians (EMTs) have been trained to use either manual or automated defibrillators. At about the same time, the use of AEDs by minimally trained first responders (usually firefighters) became more frequent. A review of pertinent studies evaluating firefighters and others using AEDs is given in Table 1. In general, adding firefighter or EMT defibrillator capability to existing advanced cardiac life support (ACLS) paramedic response led to improved survival rates, although these data are mainly derived from studies done in Seattle and King County, Washington. It is unclear whether all areas will achieve similar benefit.

USE OF AEDS BY LAW ENFORCEMENT PERSONNEL. Law enforcement personnel provide cardiac arrest first-responder care in an increasing number of communities. Recently, this has often included training and equipping with AEDs. The number of published studies evaluating law enforcement defibrillation is limited. Table 1 reviews these studies. The two published studies have shown variable results in time response intervals and survival with law enforcement AED use (28,36). Use of AEDs by law enforcement personnel needs to be supported by the chain of survival if benefits are

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**Table 1.** Automatic External Defibrillators by Nonmedical First Responders

| Provider | Intervention | Study Type | Outcome | References |
|---|---|---|---|---|
| Firefighter | BLS/ defibrillation | Meta-analysis | Improved survival to hospital discharge | 31–33 |
| Police | Defibrillation | Historic control | Improved survival as compared with baseline | 28,34–39 |
| Airline personnel | AED | Observational study | Significant survival rate (33%) | 40–42 |
| Casino personnel (trained security guards) | AED | Observational study | Significant ROSC rate (70%) | 43,44 |

ROSC = return of spontaneous circulation.

to be realized. In areas where time intervals to defibrillation are not altered with law enforcement AED use, no benefit should be expected.

**DEFIBRILLATION ABOARD COMMERCIAL AIRCRAFT.** The number of deaths per year on commercial airlines due to medical emergencies is not well defined, but estimates range from 72 to 1,000 per year, with most of them being sudden (40,45).

A number of factors unique to airline travel may exacerbate medical conditions, including stress of flying, exertion in getting from one gate to another (especially when carrying luggage), circadian disruption and reduced oxygen in the cabin (equivalent to 6,000 to 8,000 feet). Furthermore, the aircraft cabin is poorly designed for recognition and treatment of cardiac arrest. The most important limitation in delivering treatment to cardiac arrest victims has been the lack of access to defibrillation. Under the best of circumstances, it takes 20 min to divert for an emergency landing and another 10 to 15 min to reach a gate.

In 1990 and 1991, Virgin Atlantic and Qantas airlines, respectively, began placing AEDs on their aircraft. There were 27 deaths on Qantas aircraft, and only 16 (59%) of these were "witnessed." The initial rhythm was asystole or pulseless idioventricular rhythm in 21 arrests (78%). Six passengers were in VF, with five immediately converted and two surviving long term (40). In addition, Qantas placed AEDs near its terminal gates. There were 19 arrests in the terminal, all witnessed, with 17 (89%) revealing VF as the initial rhythm. Four of these patients (24%) survived long term. In comparison with the experience aboard aircraft, the higher percentage of those with VF as the initial rhythm and the longer term survival reflect the fact that cardiac arrest in the terminal is more likely to be recognized and treated immediately.

In July 1997, American Airlines became the first U.S. carrier to place AEDs aboard its aircraft, with flight attendants trained in AED use. In the first nine months of the program, the AED was used on cardiac arrest victims aboard the aircraft 42 times and in the terminal on six occasions. Seven individuals were in cardiac arrest: four were in asystole or agonal rhythm and three had VF. One of the three patients with VF has survived long term. It is important to note that the device was placed during stable rhythms in 41 individuals, but no inappropriate shock was advised or delivered (41).

**EXTERNAL DEFIBRILLATORS IN CASINOS.** Security officers in the gaming establishment can use AEDs to achieve collapse-to-defibrillation intervals shorter than those feasible with traditional prehospital EMS systems. Security officers trained by the Clark County Fire Department (Nevada) yielded mean collapse-to-defibrillation intervals of 2.2 min in 10 cases of witnessed VF. Seven (70%) of the 10 victims survived to hospital discharge (43). The program has subsequently been expanded, with the result that later adopters of the program have demonstrated longer collapse-to-defibrillation intervals and lower rates of survival after witnessed VF. The following conclusions can be drawn from this experience:

1. Rapid defibrillation can be achieved by appropriately trained and motivated casino security officers, resulting in high rates of survival.
2. Sufficient devices must be installed and located on site to enable the arrival of an AED at the victim's side in ≤3 min.
3. The interval from call for assistance to arrival of an AED must be tested prospectively from a representative set of locations on each site.
4. Optimal initial and refresher training intervals for non-traditional defibrillation providers remain to be established.
5. Integration of rapid defibrillation programs with local EMS services is necessary.
6. Physician oversight of casino defibrillation programs needs to be addressed.

**USE OF AEDS AT GATED COMMUNITIES, RESORTS AND LARGE PUBLIC GATHERINGS.** Public access to AEDs has been implemented in a number of Palm Springs country clubs under the auspices of a Coachella Valley-Wide Resuscitation Project (M. Weil, personal communication,

1999). Over the past four years, 10 golf resorts have acquired AEDs as part of this community resuscitation program. A total of 233 security and club personnel were trained (23.3 persons per site); 29 defibrillators are currently in use (2.9 defibrillators per site). A population of 16,640 individuals is covered (averaging 1,664 persons for each site). The mean age of this population is 63.7 years (range 54 to 82). One defibrillator covers 574 individuals. There is one defibrillator for an average of eight trained rescuers. The cost of implementation was $11,030 per club, including training, or ~$6.62 per member. Annual expenses were ~10% of the implementation cost ($1,100 per club and 66 cents per member). Club personnel arrive at the scene within 3.5 min (range 1 to 5), and professional rescuers after an additional interval of 6 min (range 4 to 8). The AEDs have been used on six occasions. Defibrillation was required and successfully resuscitated one victim before the arrival of professional rescuers. The victim survived with hospital discharge and no neurologic impairment. The remaining five cases represented preparedness to defibrillate in settings of acute dyspnea (n = 4) and syncope (n = 1).

LAY PUBLIC DEFIBRILLATION—BARRIERS AND SOLUTIONS. Although the concept of lay public defibrillation is appealing, there are certain barriers to consider. Is it possible that use of AEDs by lay rescuers may harm either the patient or the operator? What is the likelihood that some collapse will be misdiagnosed as VF? Previous work has shown that the rhythm detection algorithms in the AED devices are excellent for distinguishing VF and non-VF rhythms. In one out-of-hospital cardiac arrest series, 103 of 106 "shockable" rhythms were recognized and a shock was delivered (46). The three cases of VF that were not shocked were all in-patients with pacemakers, where the pacer spikes were superimposed during VF. In contrast, no shock was advised or delivered in all 950 cases of "nonshockable" rhythms, including asystole (427 [45%] of the 950). How much harm is done to a cardiac arrest victim who is shocked mistakenly? These and a number of other questions also remain. Can VF be caused by a mistaken shock? What level of defibrillation should be used for children? If a lay person is harmed by improper defibrillation, who is liable?

It is probable that the selected lay person who is highly motivated and capable of operating a defibrillator will need to undergo retraining. Laws need to be passed to indemnify individual operators, training centers and their personnel and locations where defibrillators are used. Such "good Samaritan" laws are currently in place in some states, but not all. Federal statutes may also be needed.

An additional cadre of questions arises around the actual administration of lay public defibrillation programs. Who will control the development and implementation of defibrillator programs for the lay public? Organizations with appropriate physician expertise, such as the American College of Cardiology (ACC) and American Heart Association (AHA), could assume leadership.

USE OF AEDS BY NONTRADITIONAL PROVIDERS. The potential efficacy of early defibrillation by nonmedical first responders has been demonstrated by numerous studies. There now exists compelling evidence that AEDs can be safe and effective when used by first responders, including police, firefighters and first-tier EMS providers. However, although the results are largely favorable, they are not uniformly so. The studies without favorable results highlight the importance of the incremental time gained by employing nontraditional providers of AEDs, as well as the importance of all links in the "chain of survival," to obtain improved results with early CPR and early defibrillation. One important yet unresolved issue is the proper interposition of CPR and incorporation of AEDs. Should defibrillation always take precedent or should a period of CPR sometimes be done before defibrillation attempts? Experimental laboratory studies, as well as one recently published study in humans by Cobb et al. (30), indicated that for individuals with cardiac arrest >5 min, a short duration (60 to 90 s) of chest compression is indicated before attempting defibrillation.

The need for AEDs in large populations will depend on the number of those at risk. In 1986, AEDs were made available at the World's Fair in Vancouver, British Columbia. With 22 million visitors, there were only five cardiac arrests, two of which were due to VF and were successfully treated (47). The AEDs will be most effective in high risk populations.

An example of a high risk population appears to be elderly patients at casinos. It appears that AEDs can be effectively used in these special circumstances by nontraditional first responders. The use of AEDs by spouses and family members of patients at high risk for cardiac arrest has been tried, but has been largely superceded by the development of effective implantable cardioverter-defibrillators.

Much work remains to be done before we can confidently suggest the optimal method for 1) deployment of defibrillators; 2) training of nonmedical responders; and 3) methods of control and supervision of AEDs. The answers to these problems will vary widely depending on geographic constraints and population density, as well as population risks. Rural, suburban and urban systems will undoubtedly need to be designed very differently.

**Use of AEDs in ambulatory care facilities.** There are no specific guidelines from accrediting organizations that provide recommendations for types of equipment and training requirements in nonhospital-affiliated outpatient facilities. Ambulatory care centers attached to hospitals fall under the auspices of the Joint Commission for the Accreditation of Health Care Organizations (JCAHCO) and use its new guidelines for hospital-based resuscitation practices.

Little research has been done, to date, regarding emergency cardiac care practices and preparedness in the outpatient setting. A study of primary care provider offices revealed that only 65% of offices had a physician or nurse

trained in BLS, and only 39% had anyone trained in ACLS (48). Defibrillation capability was only present in 6% of offices. Thirty-five percent of offices had at least one medical emergency in the two years before the study. Cardiopulmonary resuscitation was required in two cases and one death occurred. A cost analysis of providing AEDs and training of two personnel in BLS/defibrillation over a 10-year period only came to an additional 3 cents per outpatient visit.

Ambulatory care centers connected to hospitals typically do not have adequate on-site resuscitation capabilities. Appropriate equipment is lacking in many cases, and there are significant personnel issues. Most physicians and nurses in this setting are not trained in either BLS/defibrillation or ACLS. Much of the physician staff is transient throughout the day, which leaves the nursing staff as the only consistent presence. It is imperative that the personnel most likely to witness a cardiac arrest have the appropriate equipment and training to respond promptly. The most likely way to accomplish this is with the use of AEDs.

There is an emerging expectation from the public that early defibrillation capabilities be widely available. Given that the volume and acuity of patients seen in the ambulatory care setting are increasing, that staff has variable presence and training, that early defibrillation is the intervention most likely to improve survival in adult cardiac arrest and that cost is relatively low, all outpatient facilities should review their current preparedness for cardiac arrest and consider implementation of an early defibrillation program utilizing AEDs.

### *Hospital-Based Resuscitation*

It has often been assumed that hospitals function as self-contained EMS systems with respect to their management of cardiac arrest, because there is an abundance of health care providers in a defined environment. Unfortunately, because of this incorrect assumption, the process of resuscitation in the hospital has traditionally received less attention. The JCAHCO developed standards related to in-hospital resuscitation that were released in December 1998, effective January 1, 2000. The new standard TX.8 mandates that effective resuscitation practices be available throughout the hospital. The intent of TX.8 is that the mechanisms for effective resuscitation include:

1. Appropriate policies, procedures, processes or protocols governing the provision of resuscitation services.
2. Appropriate equipment placed strategically throughout the hospital close to areas where patients are likely to require resuscitation services.
3. Appropriate staff who are trained and competent to recognize the need for and use of designated equipment in resuscitation efforts.
4. Appropriate data collection related to the process and outcomes of resuscitation.
5. Ongoing review of outcomes related to resuscitation, in the aggregate, to identify opportunities for improvement of resuscitation efforts.

It is likely that these new guideline requirements for ongoing accreditation will stimulate hospitals to critically evaluate the process by which resuscitation is performed, as well as outcomes. The majority of U.S. hospitals are deficient in one or more of these areas and will require significant restructuring of their resuscitation efforts, including early defibrillation capability with AEDs.

A comprehensive hospital-based resuscitation program requires administrative and clinical support. A committee should be formed consisting of members representing different areas of participation in the resuscitation effort. This committee needs to have direct-line authority to someone within the hospital administrative structure who cannot only support improving the process of resuscitation from both the financial and procedural standpoint, but who can also follow through to make sure that appropriate policies are enforced. The committee also needs to have a strong quality improvement program to ensure that the process of resuscitation is appropriate and to provide a basis for feedback to personnel on the resuscitation team. The JCAHCO now requires both of these processes.

The physical layout of the institution must be evaluated, along with the patient population and staffing, to determine the best way to provide timely defibrillation. Hospital practice must shift from having CPR as the sole form of BLS to including defibrillation as a BLS skill. Delayed defibrillation occurs much less frequently in critical care areas than on general floors, and this should be taken into account when equipment choices are made. The AHA recommends that hospitals should aim for a goal of delivering the first shock within 2 min of when the arrest was determined in noncritical care areas (49).

There are adequate published data detailing that nurses can be trained to use an AED appropriately and that they can retain these skills over time. However, merely having AEDs and nursing staff trained to use them is not enough. From the clinical perspective, there appears to be significant reluctance by many nurses to use the devices. One barrier that must be overcome for a successful hospital-based AED program is re-education and an "unlearning" of previously learned behavior. The magnitude of this process should not be underestimated.

Documentation of resuscitation efforts in the hospital is typically inadequate and often inaccurate. Hospitals should develop a documentation form specifically designed to collect information on the process of resuscitation, as well as any other information pertinent to their local quality improvement. There needs to be widespread education on documentation of events during a cardiac arrest. This education needs to include training on how to use the specific documentation record, as well as the importance of accurate information. Because the form used becomes a medicolegal record, it is imperative that steps be taken to

ensure completeness and accuracy. The same documentation form should be used throughout the hospital and should include critical care areas as well.

The timing of events during in-hospital resuscitation is one of the most important and least accurate parts of documentation. There are typically several time intervals used to document events during in-hospital resuscitation efforts. Typically, someone from the hospital begins timing events with their watch while waiting for the official code team to arrive. There is also likely to be an initial time event that gets documented by the hospital page operator as the official start time. When the person responsible for documentation arrives on scene, a third time piece is often used to document events.

There will be considerable inaccuracies, unless these time pieces are synchronized. This has significant ramifications from both a medicolegal as well as a quality improvement perspective. The vast majority of hospitals have no method of time synchronization, and therefore most data regarding time to therapy may not be accurate.

Quality improvement and feedback are an integral part of the resuscitation process in the hospital and are now required by the JCAHCO. Many hospitals currently do not support this process and must quickly change their ways to be in compliance with the new standards. A good quality improvement process includes complete and accurate documentation, retrieval of documentation forms from all areas of the hospital (including intensive care units), personnel trained to understand the process of ACLS who can critically review the documentation record, a data base for collection and trending of data and a method for providing feedback to those performing resuscitation.

The National Registry of Cardiopulmonary Resuscitation offers, for a small fee, an electronic data base specifically designed for data collection of in-hospital cardiac arrest events. It is based on the Utstein Guidelines for Documentation and Reporting of Events for In-Hospital Resuscitation, but is also applicable for pediatric populations. The Registry provides precise definitions for all entries and thus lessens the confusion when comparing data from different institutions. Participating hospitals enter data from each cardiorespiratory arrest into the electronic data base. This information is sent confidentially to the coordinating center, which will then prepare quarterly reports for each hospital. Reports not only include information pertinent to each hospital's quality improvement program, but also provide benchmark information comparing similar institutions. This is the first large-scale data base of information and will likely be able to fuel data-driven guidelines on hospital-based resuscitation and ACLS. The process of improving resuscitation in the hospital remains in its infancy.

### *Pharmacologic Adjuncts to Defibrillation*

The prognosis is ominous for a sizable proportion of patients with cardiac arrest in whom spontaneous circulation is not restored by the first few defibrillation shocks and in whom additional ACLS measures, such as endotracheal intubation, epinephrine and antiarrhythmic medications, are required.

**Antiarrhythmic drugs.** Antiarrhythmic drugs, including lidocaine, bretylium, magnesium and procainamide, have been classified as an "acceptable, probably helpful" treatment for cardiac arrest secondary to ventricular tachyarrhythmias unresponsive to three or more shocks under current ACLS guidelines. Although these drugs represent current clinical practice in the U.S., there is limited evidence supporting the benefit from use of these agents in treating cardiac arrest victims. Use of antiarrhythmic agents has not been universally embraced as an essential component of treatment algorithms for shock-refractory cardiac arrest.

Evidence supporting any clinical benefit from early administration of antiarrhythmic drugs in cardiac arrest is scarce. In early animal trials, either resuscitation of VF was not improved by the addition of procainamide or lidocaine, or any benefit was offset by worsened short-term survival attributed to the drugs' adverse circulatory depressant effects. Ironically, lidocaine, procainamide, quinidine, phenytoin and oral and higher doses of intravenous amiodarone (10 mg/kg body weight) have all been observed to increase the defibrillation threshold and, in theory, make it more difficult to resuscitate hearts from VF (50–55).

In the only published case-controlled clinical trial in which shock-refractory victims of out-of-hospital VF were stratified according to those who did and those who did not receive lidocaine, no significant differences were observed in the return of an organized rhythm, admission to the hospital or survival to hospital discharge between the treatment groups (56). A retrospective evaluation of antiarrhythmic drug use during a trial of active compression–decompression CPR found that lidocaine and bretylium were independently associated with a lower likelihood of survival to 1 h after cardiac arrest (57). Another retrospective study comparing outcomes from a time when ambulances were or were not staffed by personnel who were authorized to give medications found that recipients of lidocaine were more likely to have a return of spontaneous circulation and to be admitted to the hospital, although no survival benefit was demonstrated (58). In contrast, in a prospective, randomized trial comparing administration of lidocaine with standard doses of epinephrine in shock-refractory VF, not only was there absence of benefit, but survival actually worsened when such pharmacologic therapies served to delay defibrillation (59).

The current recommended use of magnesium in torsade de pointes is supported only by case reports. Two recent prospective, double-blind, randomized trials of cardiac arrest in patients in the hospital and in the Emergency Department found no benefit from routine treatment with magnesium (60,61). Finally, none of the reported randomized trials comparing bretylium with placebo or with lido-

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**Table 2.** Biphasic Versus Monophasic Waveforms for Out-of-Hospital Defibrillation

| Waveform | Study Type | Outcome | References |
|---|---|---|---|
| Monophasic-DS | Randomized: 175 J vs. 320 J | First shock defibrillation success rates 175 J = 61%; 320 J = 61% | Weaver et al. (65) |
| Biphasic-IC | Case series | First shock defibrillation rate 89%<br>All shocks defibrillation rate 80%<br>Return to pulse in 56% | Poole et al. (66) |
| Biphasic vs. monophasic | Case series, retrospective | First shock defibrillation rates: monophasic 75%; biphasic 83%<br>All shocks defibrillation rate: monophasic 74%; biphasic 91% | Gliner et al. (67) |
| Biphasic vs. monophasic | Randomized, clinical trial | Defibrillation rate within three shocks: monophasic 67%; biphasic 98%<br>Survival to hospital discharge: monophasic 32%; biphasic 28% | Schneider et al. (68) |

DS = damped sinusoidal; IC = impedance compensating.

caine in victims of cardiac arrest demonstrated any significant differences in outcome between treatment groups (62).

In most studies to date, intravenous amiodarone has been administered only after failure of other antiarrhythmic medications to terminate malignant ventricular tachyarrhythmias. When compared with additional lidocaine and epinephrine in dogs with shock-refractory VF pretreated with prophylactic lidocaine, intravenous amiodarone significantly improved the success of subsequent defibrillation (63). The Amiodarone in out-of-hospital Resuscitation of REfractory Sustained ventricular Tachyarrhythmias trial (ARREST), a recently published randomized, prospective, double-blind, placebo-controlled trial, evaluated intravenous amiodarone in out-of-hospital cardiac arrest due to VF or pulseless ventricular tachycardia (64). In 504 randomized patients, a significant improvement in admission to hospital was observed in recipients of intravenous amiodarone as compared with placebo (44% vs. 34%, $p = 0.03$). The trial was underpowered to detect differences in survival to hospital discharge between the two treatment groups, which tended to favor recipients of intravenous amiodarone. However, this is the only randomized, placebo-controlled clinical trial ever to show a significant benefit from antiarrhythmic drug therapy during CPR.

**Conclusions.** With the possible exception of intravenous amiodarone, available evidence is inconclusive concerning benefit of antiarrhythmic drugs in cardiac arrest. Most studies addressing this question have been unpowered either to demonstrate or necessarily exclude benefit from such treatment or to have employed a positive but equally unproven control (lidocaine) comparison. The dose and manner in which to administer antiarrhythmic medications during cardiac arrest and the optimal variables by which to measure benefit from treatment (e.g., return of spontaneous circulation, admission alive to the hospital, 24 h survival, discharge from the hospital, neurologic function at hospital discharge, one-year survival) also remain controversial.

### *Emerging Defibrillation Technologies*

Electrical defibrillation of the heart was first accomplished by using epicardial electrodes in the operating room. Subsequently, transthoracic defibrillation by using first alternating and then direct current was introduced, with the latter becoming the clinical standard. A damped sinusoidal monophasic waveform has been the most commonly used waveform in commercial external defibrillators. Experience with implantable cardioverter-defibrillators indicated that a biphasic waveform achieved lower defibrillation thresholds in many patients. External defibrillators that use biphasic waveforms have recently been introduced into clinical use. Experimental studies in animals and humans, including three clinical trials comparing biphasic with monophasic waveforms in out-of-hospital cardiac arrest, have shown that lower energy is required for successful defibrillation with biphasic waveforms (Table 2).

Both monophasic and biphasic defibrillation may employ a variety of waveforms (e.g., damped sinusoidal, monophasic truncated exponential), which may not necessarily have similar efficacy. Whether one waveform is more toxic than another has not been well established. Multiple, high energy transthoracic shocks can be associated with myocardial necrosis and electrocardiographic (ECG) changes. The latter appears to be less common with biphasic shocks of equivalent efficacy.

**Conclusions.** Defibrillation can be accomplished with transthoracic direct current shocks. The optimal waveform has not yet been determined, but biphasic shocks usually have lower energy requirements for conversion out of VF to another rhythm. It remains to be determined whether

**Table 3.** Guidelines for Economic Evaluations of Health Technologies

| | |
|---|---|
| Comparison | Intervention should be compared to existing practice. |
| Time horizon | Long enough to capture all relevant future effects of intervention. |
| Design | Acceptable to use either modeling or direct observation of costs and effects. |
| Costs | Including costs of health care services, patient time expended for intervention, paid or unpaid caregiving, travel expenses and nonhealth impacts of intervention. |
| Effects | Morbidity and mortality should be accounted for by expressing effects as quality-adjusted life years. |
| Quality of life | Quality weights should be preference-based and measured on a scale from 0 (equal to dead) to 1 (equal to optimal health) |
| Discounting | Costs and effects should be discounted to present value. |
| Sensitivity analysis | Values of variables should be varied to assess whether uncertainty about key variables could have an impact on study conclusions. |

biphasic shocks will be associated with better clinical outcomes in all situations, including pediatric cardiac arrest.

## COST-EFFECTIVENESS OF PUBLIC ACCESS DEFIBRILLATION (PAD) STRATEGIES

### *Economic Evaluation of Treatments for Sudden Cardiac Arrest*

Sudden cardiac arrest is debilitating and costly. Experts have debated which outcomes should be considered when evaluating treatments for this illness. Additional insights may be gained by considering the economics of treatments for sudden cardiac arrest.

Health economic evaluation considers the tradeoff between the costs and effects of interventions. The direct costs of treatment, the costs of subsequent medical care and the costs of long-term care should be considered. If one treatment is both more costly and more effective than another, then the difference between the two interventions is expressed as an incremental cost-effectiveness ratio. Although a variety of methods have been used to calculate incremental cost-effectiveness ratios, an expert panel has proposed guidelines that may be used to standardize these methods (Table 3) (69).

Furthermore, a treatment can be considered cost-effective in comparison with another if it is associated with an incremental cost of less than twice the average annual income per life year (i.e., approximately $50,000 per life year in the U.S.) (70).

The following data have been expressed in 1999 U.S. dollars.

**Defibrillation.** A decision analytic model combined effect estimates from a meta-analysis with cost and quality of life data to evaluate the incremental cost-effectiveness of decreasing the time to defibrillation (71). Decreasing the time to treatment by addition of firefighters able to provide CPR or defibrillation cost $63,700 per quality-adjusted life year. Decreasing the time to treatment by addition of ambulance-based providers cost $191,100 per quality-adjusted life year. These estimates were limited by the quality of the underlying effectiveness data.

Another decision analytic model estimated the incremental cost-effectiveness of decreasing time to defibrillation by implementing public access defibrillation (72). If this was implemented by using lay responders, the program cost $46,700 per quality-adjusted life year. If it was implemented by using police, the program cost $29,000 per quality-adjusted life year.

Also, decision analysis was recently used to assess the incremental cost-effectiveness of decreasing time to defibrillation by training and equipping security guards in a gaming establishment (73). Compared with usual care, early defibrillation cost $40,700 per life year, even after including all future costs.

As yet, there has been no comprehensive evaluation of the economics of defibrillation on passenger aircraft or in other public settings (e.g., golf courses).

**Advanced life support.** Two studies have evaluated the costs of advanced life support for sudden cardiac arrest. In the decision analysis described earlier, implementation of advanced life support cost $48,000 to $113,000 per quality-adjusted life year (71). On the basis of cost data collected from a retrospective case-series, advanced life support cost $13,200 per life year (74). The former analysis considered EMS costs and hospital costs, whereas the latter considered EMS costs alone.

**Conclusions.** Economic analyses of treatments for sudden cardiac arrest provide several insights into the economics of emergency cardiovascular care. First, interventions that shorten the time to defibrillation are likely to be cost-effective if achieved by a low intensity intervention such as police or lay responder defibrillation. Second, advanced life support is an effective treatment for cardiac arrest, but it is also expensive. There are conflicting data as to whether the additional benefit of ACLS justifies the additional expense. There are insufficient data to determine whether other treatments for cardiac arrest are economically attractive.

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Finally, future economic evaluations of treatments of cardiac arrest should adhere to current standards for cost-effectiveness analysis.

## CARDIAC ARREST: LEGAL AND LEGISLATIVE ISSUES

"Good Samaritan" laws were designed to protect and indemnify the unskilled provider administering BLS. The last decade, however, has shifted the burden of sophisticated patient care to the outpatient arena and to health care providers with lesser degrees of formal training. Several previously defined "ACLS" tasks (i.e., defibrillation) are now performed out of the hospital by nontraditional health care providers. These events have exposed the inadequacy of many existing Good Samaritan laws in dealing with current resuscitation practice and the potential liability for out-of-hospital health care providers and others.

In 1993, the AHA and other organizations endorsed early defibrillation. Despite this extremely strong recommendation, in 1996 and 1997, <30% of first responders nationwide were equipped with AEDs. One of the major roadblocks to implementing the AHA recommendation was that, in many states, the first responders (many times the EMT) was not *legally permitted* to defibrillate. Subsequently, numerous studies demonstrated the overall safety and efficacy of defibrillation (using AEDs) in the hands of nontraditional health care providers (31,33,75–82) and prompted several questions that warrant attention:

1. Who is a health care provider?
2. Who can defibrillate with an AED?
3. What is the legal risk for not only the user, but also the trainer or the owner of a facility with an AED?
4. Who "regulates" or monitors such PAD programs?
5. What is the manufacturer's liability if the device is used "off-label"?

**Who is a health care provider?** The AHA sponsored conferences on PAD and defined the traditional health care provider as an individual with a duty to respond as part of their professional job description (e.g., nurse, EMT). The nontraditional health care responder, on the other hand, was defined as someone who may encounter a medical emergency but is not required to respond as part of their job (e.g., airline personnel, police, security guards). It was suggested that all individuals trained in a physician-monitored AED program be allowed to defibrillate.

**Indemnification.** Individuals, however, may be fearful of litigation when using an AED or developing an AED program. Along with effective AED training, it becomes necessary to have mechanisms for immunity of not only the user, but also the provider, trainer or person who owns the AED (i.e., the AED acquirer). Both state and federal legislation has introduced immunity for AED use when implemented in programs under physician authorization.

**Federal and state legislation.** Over 42 states (as of September 10, 1999) have passed legislation that provides immunity for the traditional and the nontraditional health care provider when using an AED. Some of these laws extend this protection to trainers, acquirers, owners and other relevant individuals. These laws also support school CPR training and authorization for AED use by EMTs. All these statutes recommend that PAD programs remain under physician authorization.

If state legislation has been so effective, what is the value for additional federal legislation? The two should not be thought of as mutually exclusive, but rather as mutually supportive. State programs are limited in their scope, vary in their provisions from state to state and do not have jurisdictional control over federal facilities (e.g., military bases, Veterans Affairs hospitals, the National Institutes of Health, Indian reservations, national parks, courthouses). Federal programs, however, are able to define minimal national standards of excellence, and thus serve to standardize the quality of care nationwide. This is not a new concept, but is evident when one examines programs from the National Highway Traffic Safety Administration. In addition, federal legislation is important for identifying future jurisdictional control (i.e., issues pertaining to cardiac arrest) by virtue of being applicable nationwide, and outcomes impacted nationwide should reside at the national level.

## ADVANCED CARDIAC LIFE SUPPORT

### *Use of Pressor Agents in the Treatment of Refractory Cardiac Arrest*

Patients in VF or ventricular tachycardia (VT) who fail defibrillation and those in bradyasystolic states who fail BLS need immediate therapy to reverse the metabolic effects of ischemia on the myocardium if CPR is to be successful. Basic life support, including ventilation and chest compression, is intended to generate an adequate coronary perfusion pressure to provide improved flow of blood to the myocardium. However, BLS efficacy is limited, and frequently the clinician will need to proceed to therapy with drugs that might increase myocardial blood flow.

The immediate goal of pressor therapy is to increase vasomotor tone and increase coronary perfusion pressure to improve blood flow to the heart and brain, improving the chance of return of spontaneous circulation (ROSC) and preventing continued brain injury.

Alpha-adrenergic receptor agonists, such as phenylephrine, are powerful peripheral vasoconstrictors that redistribute blood to the brain and heart during CPR. Their effect is principally on the arterial side of the circulation, and in laboratory models they increase the rate of ROSC. Beta-adrenergic agents, such as isoproterenol, cause significant vasodilation and can worsen coronary perfusion pressure during CPR. They can also increase myocardial oxygen utilization, and thereby exacerbate the metabolic effects of ischemia. When the beta receptor is blocked before admin-